

Owner's Manual



SMARC

Your Health. We Care.

PMHC

Preventive Medical Health Care Co., Ltd.

Version: 1.0 (10/15/2018)

Foreword / Important Notice

Thank you for choosing SMARC products!

It is the owner's responsibility to ensure that all users are fully informed of all warnings and precautions. Please read this manual thoroughly before operating SMARC products. If you have any question after reading this manual, please contact customer tech support at the local authorized dealers or visit www.twpmhc.com for more details.

SAFETY

GENERAL SAFETY

1. Be cautious when getting on and off equipment seats to avoid falling.
2. Always set up all safety devices and pull the armrests down before exercising. For users with poor control of trunk and limbs, make sure the seat is in locked position.
3. To prevent injuries, follow the instructions below:
 - Never place hands close to the seat base when rotating the seat.
 - Never place hands between the narrow spaces of the equipment or reach into the range of motion limiters (eg. CS101, CS103, CS105, CS107 and CS108).
 - Keep clear of the range of motion handles when the equipment is occupied.
 - Be careful when operating the equipment to avoid tripping over equipment frames (Stretching Tube of CS103).
 - Do not sit on or lean against the armrests.
 - If unusual situation has been observed (noises, no console display, loosen parts, and etc), stop operation and contact local distributors immediately.
 - Do not place the equipment outdoors or in area with high humidity.
4. Products are for continuous operation, and are not intended to be used in oxygen rich environment nor to be sterilized. Do not perform servicing and maintenance while ME equipment is in use.

ELECTRONIC SAFETY

1. This equipment must be grounded. If the equipment should malfunction or breakdown, grounding provides a path to reduce the risk of electrical shock.
2. Please unplug the power cord wire to shut down the power.
3. Improper connection of the grounding conductor can result in risks of electric shock. Do NOT modify the plug provided with the equipment. If it does not fit the outlet, have a proper outlet installed by a qualified electrician.
4. Pulling on the cord can cause damage to the power cord. You should always pull on the actual plug.
5. With energy conservation in mind, the console will automatically go dark when SMARC product has not been used for 30 minutes. Main Page will reappear when the equipment is used again.
6. WARNING: To avoid the risk of electric shock, the equipment must only be connected to supply mains with protective earth.
7. SMARC products forms a ME SYSTEM when connected to a power supply, and can be operated at a voltage of 115V or 230 V.
8. Do not position the ME Equipment that makes it difficult to disconnect the device (eg. to unplug).

9. The USB socket on SMARC console should ONLY be connected with USB flash drive provided by PMHC and authorized dealer. It should ONLY be used with the purpose of upgrading the software. SMARC products are not suitable for connecting with any other electrical equipment. Connecting with other devices might cause potential electromagnetic interference.

PRECAUTION

FOR GENERAL CONSUMERS

1. If users experience any kind of discomfort, including chest pain, nausea, dizziness, shortness of breath, severe joint pain or muscle pain, stop training immediately and consult physician or physical therapist before continuing.
2. Warm up prior to exercise. Start exercise with light, repetitive, dynamic, site-specific movement.
3. Avoid over-stretching to prevent strain of soft tissues and joint instability.

FOR PATIENTS WITH MEDICAL NEEDS

Patient may be the intended operator, in this case, please operate SMARC products under supervision of physicians or physical therapists.

Users with following medical and therapeutic needs (especially over 40 years old) should consult physician or physical therapist before operating.

1. Inflammation: Patients with inflammatory neuromuscular disease such as Guillain-Barre disease, Polymyositis, and Dermatomyositis should use low Resistance training.
2. Severe cardiopulmonary disease: Patients with acute symptoms such as but not restricted to the following should not attempt Resistance training.
 - Coronary artery disease (unstable angina, myocardial infarction)
 - Carditis
 - Cardiomyopathy
 - Aortic stenosis and Aortic dissection
 - Decompensated congestive heart failure
 - Severe pulmonary embolism
 - Unstable hypertension
 - Ventricular arrhythmia
3. When a hematoma or other indication of tissue trauma is observed.
4. Musculoskeletal Disorder: Patients who recently had a fracture, and bony union is not completed. A bony block limits joint motion.
5. Neurological Disorder Patient: Only patients with good static sitting balance or Brunnstrom stage above III are recommended using SMARC products.
6. Do not set high Resistance for children, elderly, and patients with osteoporosis.
7. Be aware of medications a patient is using that can alter acute and chronic responses to exercise.
8. The equipment might emit low intensity electromagnetic pulse. Patients with concern should consult physician or physical therapist before operating.

FCC statement

Federal Communications Commission (FCC) Statement

15.19

This device complies with Part 15 of the FCC Rules.

Operation is subject to the following two conditions:

- 1) this device may not cause harmful interference and
- 2) this device must accept any interference received, including interference that may cause undesired operation of the device.

15.21

You are cautioned that changes or modifications not expressly approved by the part responsible for compliance could void the user's authority to operate the equipment.

15.105(b)

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help

FCC RF Radiation Exposure Statement:

1. This Transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.
2. This equipment complies with RF radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with a minimum distance of 20 cm between the radiator and your body.

“SMARC” is a complete series of 8 Accommodating Functional Movement training equipment designed to improve functional capacity, quality of motion and cognitive level with its integrated hardware and software combination. Improvements in coordination, balance, functional capacity enhancement, flexibility, functional strengthening, cardiopulmonary function, etc. can be observed.

CLASSIFICATION & CERTIFICATION

SMARC products are CLASS I medical equipment (non-invasive) manufactured by an ISO 13485 certified factory.

All applied parts of SMARC products are TYPE B APPLIED PARTS:

CS101: Palms and buttocks

CS102: Buttocks and back

CS103: Palms and buttocks

CS104: Palms and buttocks

IP classification: IPX0

CS105: Palms and buttocks

CS106: Palms and buttocks

CS107: Palms and buttocks

CS108: Palms and buttocks

Medical CE

USA FDA registered establishment and FDA enlisted products

Taiwan FDA approval (Class I Medical Device)

TUV Certification

IEC 60601-1: 2005+A1, EN 60601-1: 2006+A11+A1+A12 (T-mark)

CAN/CSA-C22.2 No. 60601-1:2014, ANSI/AAMI ES60601-1:2005 + A2 (R2012) + A1 (cTUVus)

IEC/EN 60601-1-2: 2007 (C.o.C.)

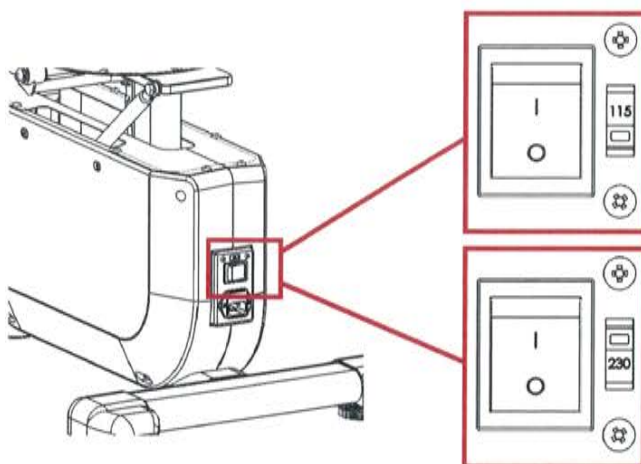
DIN EN ISO 20957-1: 2014-05, EN 957-2: 2003

FCC ID:2ARC9CSMARC

This owner’s manual is written for patients over 15 years old with complete knowledge of the local language.

Important Notice

Always switch to appropriate voltage before switching-on.



Please switch voltage to 115V for countries with city power supply between 100V to 120V.
Eg. USA, Canada, Taiwan and so on.

Please switch voltage to 230V for countries with city power supply between 220V to 240V.
Eg. England, Germany, China and so on.

Asia Pacific Region

Japan: 100 V / Taiwan: 110V / Vietnam: 120V

Other Asia Pacific countries: 220V

North American Region

110V

South American Region

Brazil / Paraguay / Uruguay / Argentina / Chile : 220V

Other South American countries: 110V

Middle East / European / African Region

220V

Application (USE ENVIRONMENT) – Operation ambient

Operation:

Environment for SMARC products operation:

SMARC products are designed for medical rehabilitation. Please do not operate the equipment in environments with temperature > 35°C.

a. Environment:

(a) General: Hospitals.

(b) Condition of visibility:

i. Ambient luminance 100 – 500 lux

ii. Viewing distance 20 cm to 1 meter

iii. Viewing angle: normal to the scale ± 20°

iv. The temperature / Humidity Requirements for product operation: -30 ~ 35°C / 20% < RH % < 95%.

(c) Physical: Normal ambient conditions

b. Frequency of use:

One training session (10 mins) a day to up to 3 training sessions (30 mins) a day.

Mobility: SMARC products is a stationary medical equipment, it is not designed for mobility while in use.

Warning Signs

LABELS ON CARTON



Labels on carton for transportation reference for unwrapping the product.



This way up



Keep dry



Handle with care



Maximum 2 layers stacking



Fragile material

LABELS ON THE PRODUCT



Please read Owner's Manual before operation.








Warning label on console: Please read Owner's Manual before operation.

In case users do not read the Owner's manual before transportation, a warning sign is marked on Console.



CS103 Steel Tube tripping warning:

To prevent users from tripping over the steel tube.

<p>Medical Rehab Equipment Trademark: SMARC Product Name: Cloud SMARC Model No.: CS101 FCC ID No. : 2ARC9CSMARC</p> <p>Input Rating: 110-120 / 220-240 Vac, 50/60Hz, 0.75 / 0.35A</p> <p>Medical Device Type: Class I Maximum Weight Load: 150 kg PREVENTIVE MEDICAL HEALTH CARE CO., Ltd. No. 88, Ln. 430, Yongchun S. Rd., Nantun Dist., Taichung City 408, Taiwan Manufacture date (MM/DD/YYYY):</p> <p>1609-101-008001008 MADE IN TAIWAN</p>		 <p>EN 60601-1 IEC 60601-1</p> <p>www.tuv.com ID 1419033621</p>
		
		
	 	 <p>Compliant EEC 93/42 Directive</p>



Type B applied part



Medical CE



Caution



cTUVus marking



QR code for TUV certificates



TUV certificate number and marking

Fuse type: UFE / UFE-A series
 Voltage (V): 250V AC
 Current (A) rating: 3.15A
 Operating speed: F
 Breaking capacity: L

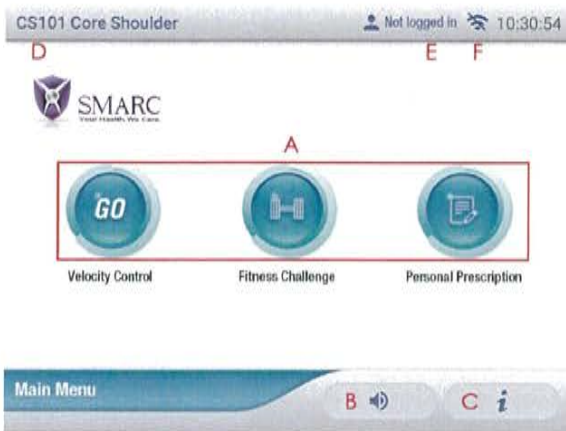
Fuse type information

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Console Function

1. Main Menu



1.1 Functional Keys

- A. 3 different training modes: GO (Velocity Control) / Fitness Challenge / Personal Prescription
- B. Volume Control
- C. i : Information

1.2 Console Display

- D. Model Name
- E. Log-in Information
- F. wifi Connection Status

2. Training Page



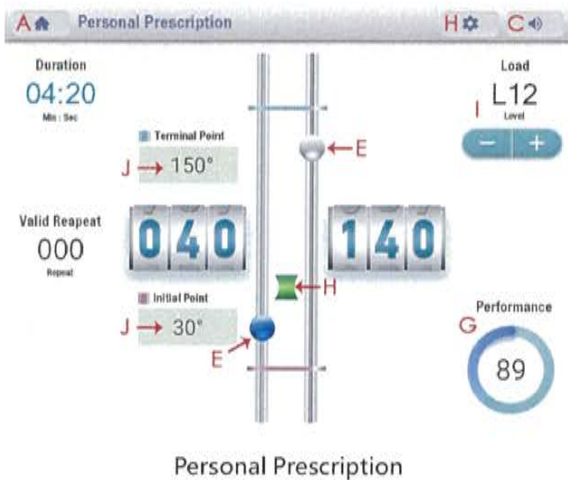
2.1 GO / Velocity Control

- A. Exit: Stop the training. (The training cannot be continued once the button is clicked)
- B. Reset: Reset all the training parameter and data. (only in GO/ Velocity Control mode)
- C. Velocity:
 - Preset value: Press + and – to adjust.
 - Actual value: This indicates user's actual velocity of training body parts (unit: °/s).
 - Color unchanged: Resistance remains unchanged when Target Velocity > Actual Velocity > Target Velocity – 10°/s.
 - Color red: Resistance increases by 1 level each repeat when Actual Velocity ≥ Target Velocity.
 - Color green: Resistance increases by 1 level each repeat when Target Velocity – 10°/s > Actual Velocity.



2.2 Fitness Challenge

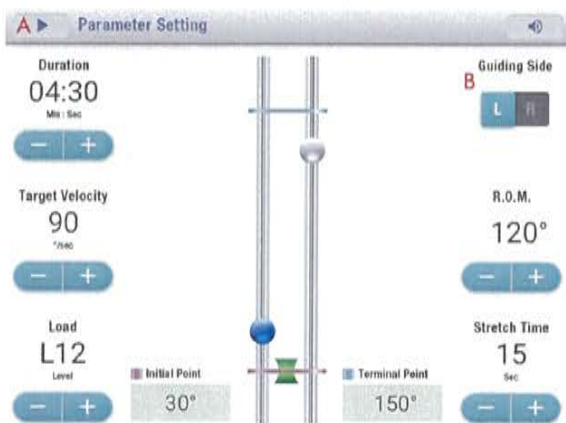
- D. Green Velocity Target: Green Velocity Target constantly moves back and forth on the Motion Track. Users need to move the Blue Tracking Ball to catch up with the Green Velocity Target.
- E. Tracking Ball: 3 different colors for different statuses.
 - Blue color: represents the guiding side, indicating the current position. Users need to move the Blue Tracking Ball to catch up with the Green Velocity Target for training (in Fitness Challenge mode & Personal Prescription mode).
 - Green color: when the Blue Tracking Ball and Green Velocity Target align, the Blue Tracking Ball turns green.
 - White color: represents the other symmetrical side, also indicating its current position.
- F. Training Grade: there are totally 20 grades. Press + and – to adjust the difficulties. Grade 20 is the most difficult grade; Grade 1 is the easiest grade.
- G. Performance Score: The performance for each repeat. The higher the score, the better the performance is.



2.3 Personal Prescription

- H. **Adjustment Key:** press to enter Parameter Setting Page (only in Personal Prescription Mode).
- I. **Resistance:** Level ranges from level 1 to level 20.
- J. **Initial Point and Terminal Point:** These values indicate preset angle of Initial Point (IP) and Terminal Point (TP).

3. Parameter Setting Page



- 3.1 This page only exists in Personal Prescription Mode.
- 3.2 After adjusting the parameter, all the training parameter and data will be reset.
- 3.3 **Functional Keys**

- A. Start: return to Training Page.
- B. **Guiding Side:** Select to switch guiding side (right/R or left/L). The Blue Tracking Ball will switch to the corresponding side.

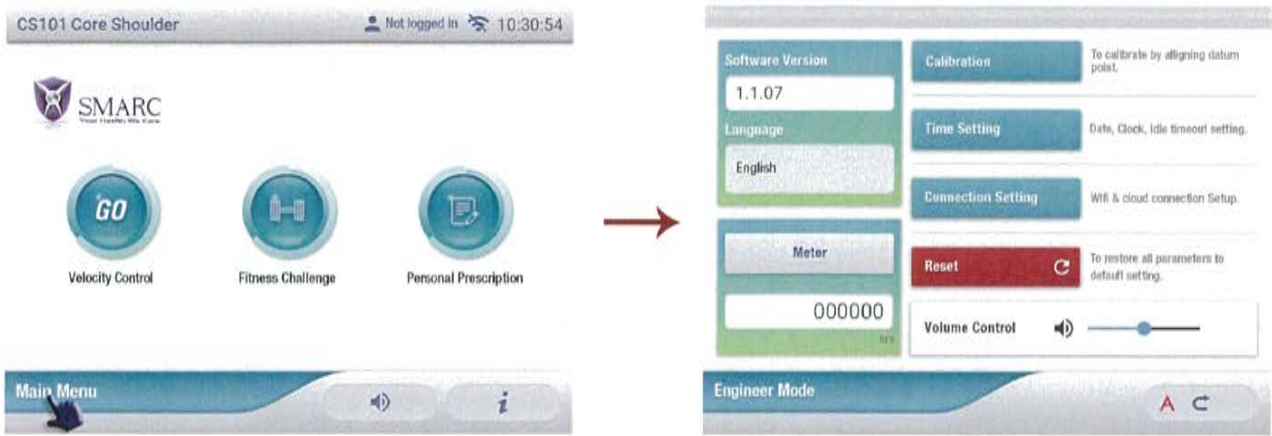
4. Summary



- 4.1 After training, Summary page will automatically pop out.
- 4.2 Scan the QR code to view the summary result.
- 4.3 **Functional Keys**
- A. Click to return to Main Menu.

Console Function

5. Engineer Mode



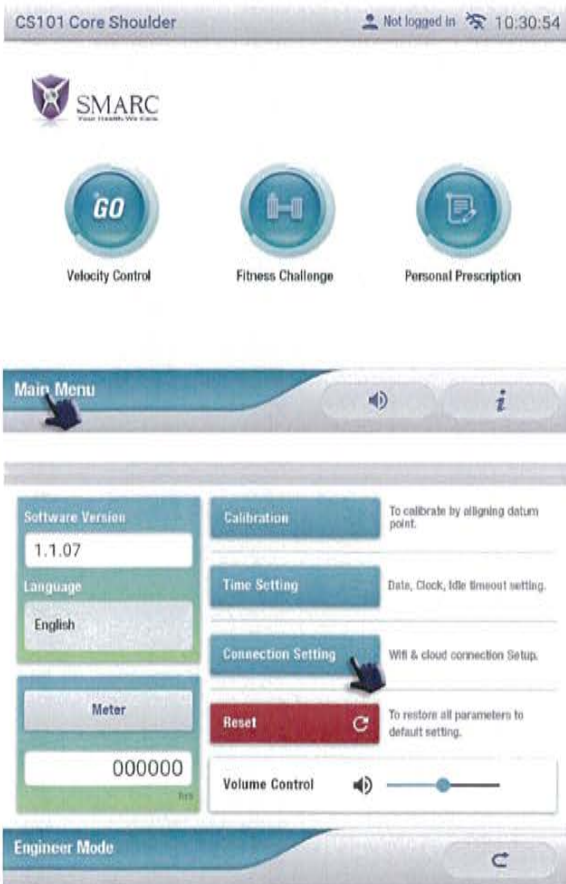
5.1 Press and hold onto the Main Menu area for 4 seconds to enter Engineer Mode.

5.2 Calibration, Time Setting, Connection Setting, Reset, Volume Control can be setup in Engineer Mode.

A. Click to return to Main Menu.

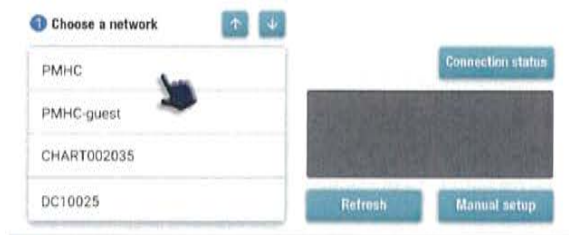
Console Operation

1. Choose a network

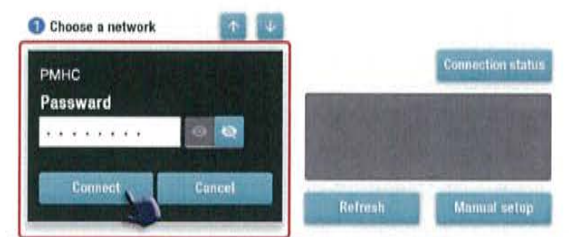


Step 1: Press and hold onto "Main Menu" for 4 seconds.

Step 2: Press "Choose a network."



Step 3: Choose network.



Step 4: Enter network password and press "Connect."



Step 5: Enter Cloud server IP and press "Refresh."



Step 6: Return to Main Menu and confirm the connection.



Velocity Control



Fitness Challenge



Personal Prescription



Console Function

2. User Log-in



Step 1: Scan the RFID card on the "right side" of the console.



Step 2: Confirm the user log-in.

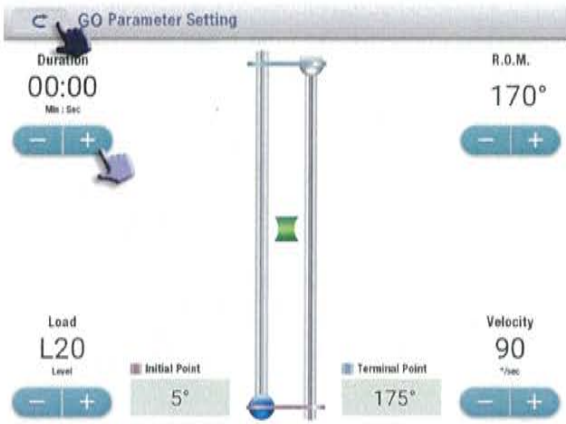
3. Parameter Adjustment



Main Menu

Step 1: Press and hold onto "GO (Velocity Control)" / Fitness Challenge / Personal Prescription for 4 seconds to enter the Parameter Setting page.

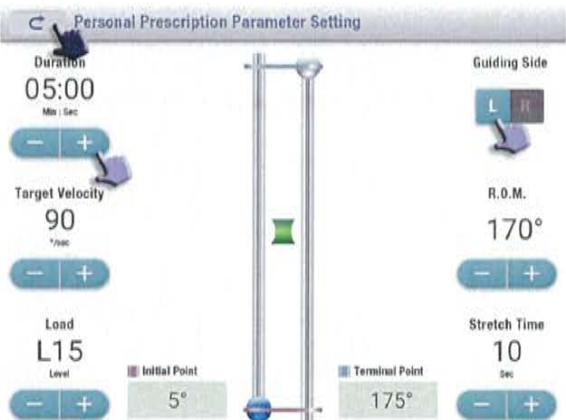
Step 2: Press + and - to adjust. Press the **left top corner** to return to Main



GO / Velocity Control



Fitness Challenge



Personal Prescription

Hardware Highlight

CS101 CORE SHOULDER



Multi-Position Handle Bars



Safety Belt



Rotation Seat Adjustment Set
(with lock device)



Wrap-Around Lumbar
Support Pad

CS102 CORE TRUNK



Multi-Position
Foot Platform



Angle Limiter



Safety Belt

CS103 CORE LOWER BACK



Angle Limiter



Rotation Seat Adjustment Set
(with lock device)



Safety Belt



Stretching Tube

CS104 CORE PELVIC



Rotational Seat
(Rotation & Tilt)



Safety Lock Device



Safety Belt

CS105 CORE GAIT



Moving Pedal Arms



Rotation Seat Adjustment Set
(with lock device)



Safety Belt

CS106 CORE HIP



Lock Adjustment Knob



Rotation Seat Adjustment Set
(with lock device)



Safety Belt

CS107 CORE KNEE



Moving Pedal Arms



Rotation Seat Adjustment Set
(with lock device)



Safety Belt

CS108 CORE TOTAL BODY



Moving Pedal Arms



Rotation Seat Adjustment Set
(with lock device)



Safety Belt

Maintenance

1. General Maintenance

- (1) SMARC products require only the most basic general maintenance, performed on an as-needed basis every 6~8 months.
- (2) **WARNING:** No modification of this equipment is allowed.
Minimum qualifications of **SERVICE PERSONNEL:** Only technicians trained by PMHC and associated distributors are supposed to do maintenance. Please contact PMHC factory or local authorized dealer for maintenance.

The **MANUFACTURER** will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist **SERVICE PERSONNEL** to repair those parts of **ME EQUIPMENT** that are designated by the **MANUFACTURER** as repairable by **SERVICE PERSONNEL**.

2. Recommended Cleaning (optional)

- (1) With the system turned **OFF**, wipe down all surfaces with a damp cloth. Neutral detergent and water can be used to remove stains and scuff marks. Inspect all locking and adjustment mechanisms for signs of damage.
- (2) **NOTE:** *DO NOT use cleaning solutions containing ammonia or alcohol to clean. Neutral detergent and water should be sufficient. Allow the system to dry thoroughly before resuming operation.*

For viewing requirements of technical description details, please refer to external technical document (16. IEC 60601-1 Technical Document of SMARC product).

Installation & Disposal

Installation

For installation procedures, please refer to Assembly Guides for detailed information. If there's any malfunction on the console, contact local authorized SMARC distributor or dealer for details.

"Assembly Guides" are enclosed in the carton box of every product.

Minimum qualifications of **SERVICE PERSONNEL:** Only Technician trained by PMHC and associated distributors are supposed to do installation. Please contact PMHC factory or local authorized dealer for installation.

Transportation during installation:

There are 2 wheels designed on "rear end cap." Based on original design, it can only be transported indoor for maximum of 10 meters.



Lift up ~35 degrees above ground level, the wheels are for short distand transportation purpose.

Disposal

Disposal procedures:

SMARC products are movement therapy equipment manufactured with steel parts, PVC foams, electronic control board, cables, plastic parts and copper plate.

There are no chemical components or toxic substances involved in manufacture of SMARC products.

Please follow the disposal regulations in different countries or regions for disposal procedure.

Manufacturer Name and Contact information:

Preventive Medical Health Care Co., Ltd. (PMHC)

No. 88, Ln. 430, Yongchun S. Rd., Taichung 408, Taiwan.

Tel: +886-4-2389-0400

Fax: +886-4-2389-0480

Intended User

Transport:

Patients are not allowed to do the transport of SMARC products.

Users:

Healthy adults.

Education: no maximum

Knowledge: minimum.

Language understanding: understand English or domestic language depends on different countries.

Experience: minimum, no special experience needed.

Professional competence: No limitation

Storage:

There's no special "intended use" for "storage of PMHC product."

Just leave SMARC equipment in the clinic after usage.

Installation:

Healthy adults.

Education: no maximum

Knowledge and experience: Certificated technician trained by PMHC.

Language understanding: understand English or domestic language depends on different countries.

Operation:

Age: 15 + years old patients

Gender: both

Weight: less than 150 kg.

Patient state: mentally stable.

Cultural background: No limitation

Level of education: No limitation

Professional competence: No limitation

Limitation:

Users with following medical and therapeutic needs (especially over 40 years old) should consult physician or physical therapist before using the product.

Inflammation: Patients with inflammatory neuromuscular disease such as Guillain-Barre disease, Polymyositis, and Dermatomyositis should use low Resistance training. Whenever there is evidence of an acute inflammatory or when soft tissue healing could be disrupted in the tight tissues and surrounding region, dynamic resistance exercise should be forbidden.

Severe cardiopulmonary disease: Patients with acute symptoms such as but not restricted to the following should not attempt Resistance training.

When a hematoma or other indication of tissue trauma is observed.

Musculoskeletal Disorder: Patients who recently had a fracture, and bony union is not completed. A bony block limits joint motion.

Neurological Disorder Patient: Only patients with good static sitting balance or Brunnstrom stage above III are recommended using SMARC products.

Do not set to high Resistance during exercise for children, older adults, and patients with osteoporosis.

- Coronary artery disease (unstable angina, myocardial infarction)
- Carditis
- Cardiomyopathy
- Aortic stenosis and Aortic dissection
- Decompensated congestive heart failure
- Severe pulmonary embolism
- Unstable hypertension

All patients should be supervised by medical professions.

Maintenance and repair

Certificated technician trained by PMHC.

Education: no maximum

Knowledge and experience: Certificated technician trained by PMHC.

Language understanding: understand English or domestic language depends on different countries.

Disposal:

Patients are not allowed to do the disposal of SMARC products.

Users: Healthy adults.

Education: no maximum

Knowledge: minimum.

Language understanding: understand English or domestic language depends on different countries.

Experience: minimum, no special experience needed.

Professional competence: No limitation

Operating Principle

Physical methods used to accomplish its INTENDED USE

CS101: USERS hold the handle bars. Using shoulder joints to initiate the flexion-extension movement of shoulder joints to achieve movement therapy session.

CS102: USERS lean on the back pad. Using lower extremities to initiate the flexion-extension movement of pelvic joint to achieve movement therapy session.

CS103: USERS hold the handle bar. Using shoulder joints to initiate the flexion-extension movement of shoulder joints to achieve movement therapy session.

CS104: USERS sit on the rotational seat. Using core muscles to initiate the rotational movement of trunk to achieve movement therapy session.

CS105: USERS step on pedals. Using lower extremities muscles to initiate the flexion-extension movement of pelvic joints to achieve movement therapy session.

CS106: USERS step on pedals. Using lower extremities muscles to initiate the abduction-adduction movement of pelvic joints to achieve movement therapy session.

CS107: USERS step on pedals. Using lower extremities muscles to initiate the flexion-extension movement of knee joints to achieve movement therapy session.

CS108: USERS hold the handle bars and step on pedals. Using upper extremities and lower extremities muscles to initiate the flexion-extension movement of upper extremities and lower extremities to achieve movement therapy session.

Mechanisms by which it works

SMARC products are movement therapy equipment. During operation, it allows USERS to sit on the equipment and perform various movement therapy training on various joints.

Significant physical characteristics:

SMARC products are made of steel frame, with plastic & metal covers to cover up the internal parts. The material of applied part is PVC material, which, as stated in various researches, is a chemically stable material that possess fire retarding properties.

Significant performance characteristics:

1. Reciprocal movement Pattern

- Multi-Joints
- Multi-Muscles Groups
- Multi-Planes

Maximum functional R.O.M.

Body-limbs linkage

2. EMS Resistance

“Zero” inertial force

- Safety
- Easy to start; easy to stop

Resistance is always equal in counter direction

Resistance is always against movement

3. Quantified Self

Performance feedback

- Digital biofeedback
- Real-time motion feedback
- Visual & audio sensory feedback

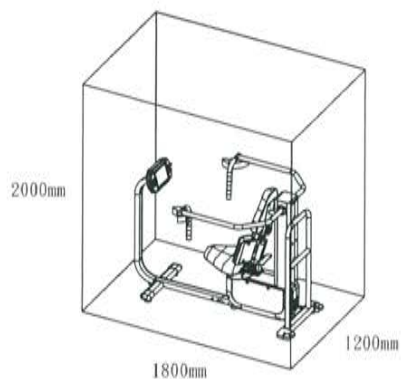
Performance data analysis

Annex A. Additional information in compliance to DIN EN ISO 20957-1:2014-05, EN 957-2:2003

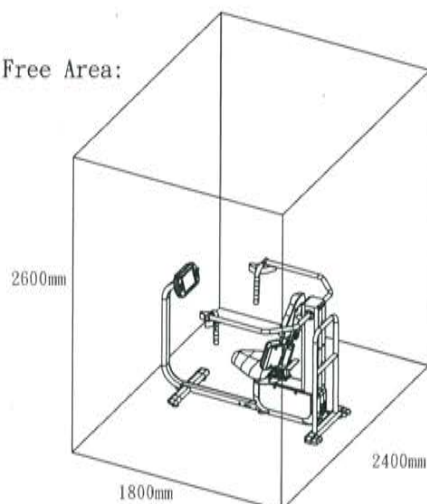
While placing SMARC products, the free area shall be not less than 0,6 m greater than the training area in the directions from which the equipment is accessed. The free area must also include the area for emergency dismount. Where equipment is positioned adjacent to each other the value of the free area may be shared. The free area and training area are illustrated as following figures.

CS101

Training Area:

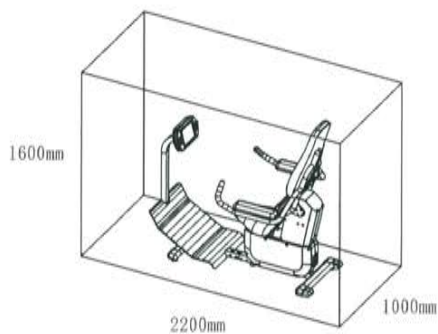


Free Area:

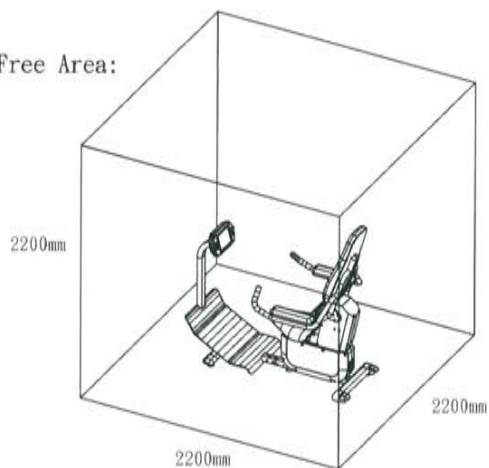


CS102

Training Area:

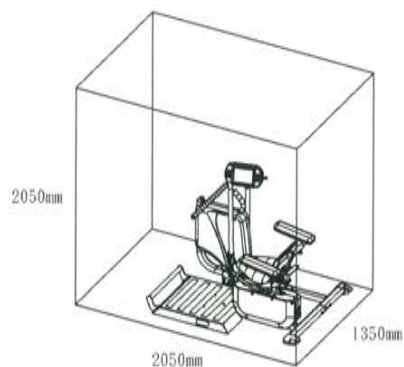


Free Area:

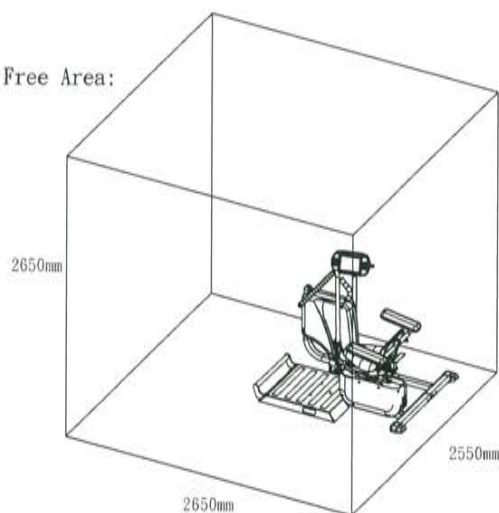


CS103

Training Area:

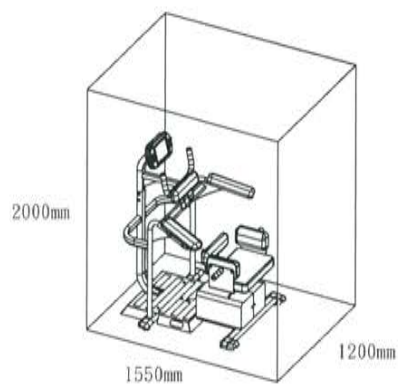


Free Area:

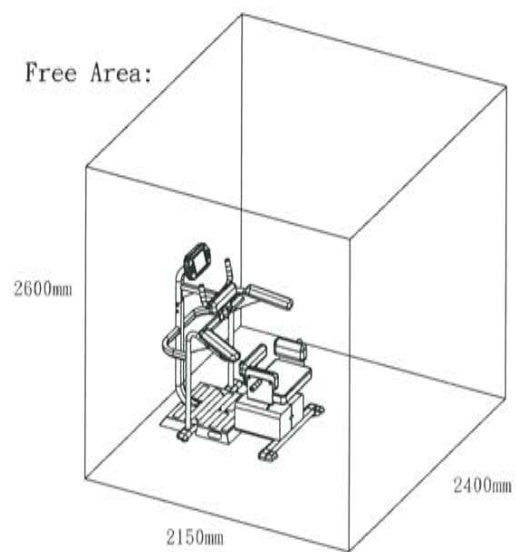


CS104

Training Area:

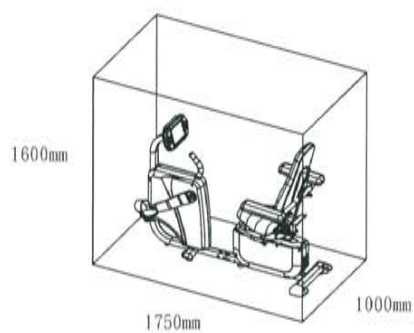


Free Area:

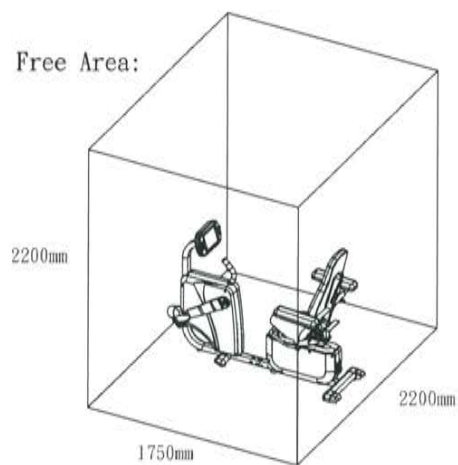


CS105

Training Area:

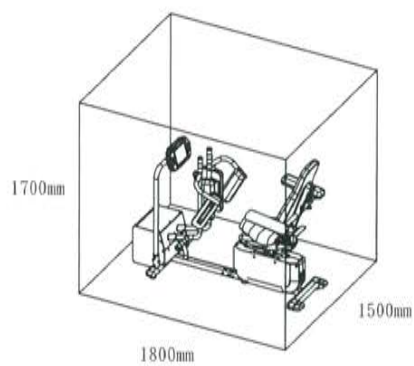


Free Area:

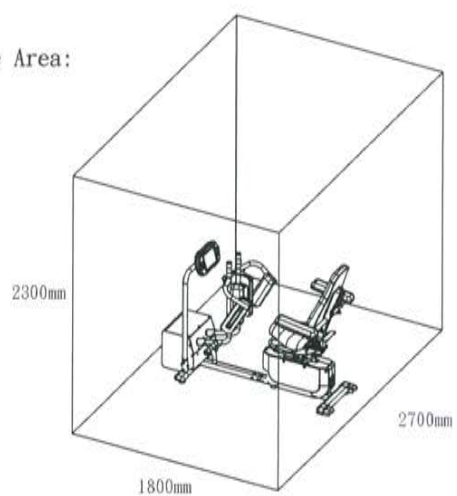


CS106

Training Area:

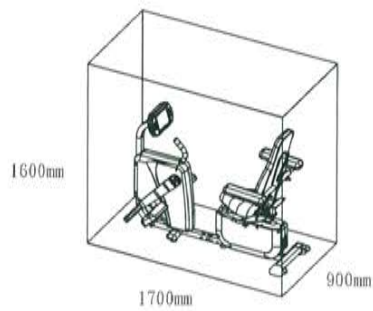


Free Area:

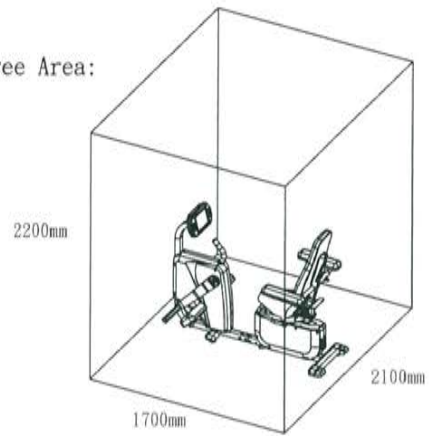


CS107

Training Area:

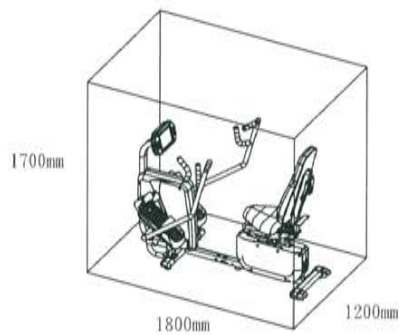


Free Area:

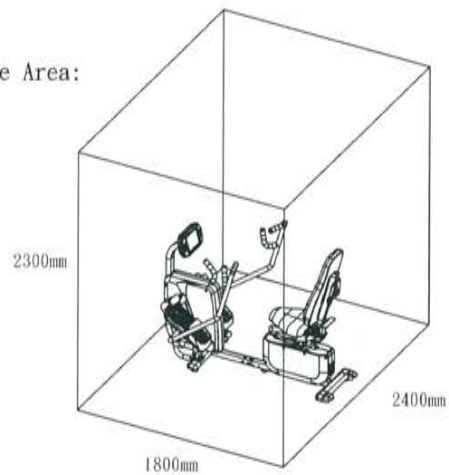


CS108

Training Area:



Free Area:



Warning: SMARC products shall be installed on a stable and levelled base.

Warning: keep unsupervised children away from the equipment. SMARC products shall only be used in supervised areas.

General Instructions of use:

Sit on the seat of each equipment, place feet on the pedals for equipment with pedals, else place feet on the stepping board or on the ground.

To get off, stand firmly on the ground and use the armrests or supporting handle as aids if necessary.

Maintenance Log :

Date	Maintenance Information	Technician Signature

Date of Purchase:

Serial Number:

Distributor Name:

Distributor Phone Number:

Distributor Address:

Distributor Stamp:
